

Draft Guidance for Industry
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products
Chemistry, Manufacturing, and Controls Documentation

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Lines 931 - 937: EXTRACTION

An extraction test ~~should~~ be performed on every incoming component batch using water and other 932
suitable solvents selected from the control extraction studies, to determine the 933
individual and total extractables.

If a correlation can be established between the extractables from the raw ~~material~~ resin batches and molded components batches, then a routine extraction control for each and every raw material batch should be acceptable, with reduced testing of individual component batches.

It is, however, appropriate to test each batch of molded components for extractables where materials are blended during the molding process.

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